# 510(K) Summary

JUL 1 1 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K123075

1. Submitter's Identifications:

Well Life Healthcare Limited
1F., No. 16, Lane 454, Jungjeng Road, Yunghe City, Taipei County 234, Taiwan, ROC

Contact: Jenny Hsieh
Telephone: + 886 2 2928 2112

Date of Summary Preparation: May 25, 2013

2. Name of the Device:

Trade/Device Name: Buttock Muscle Stimulator, model: WL-2413E.
Regulation Number: 21 CFR 890.5850
Regulation Name: Power muscle stimulator.
Regulatory Class: II
Product Code: NGX

3. Information of the 510(k) Cleared Device (Predicate Device):

SPORT-ELEC models Body Control System "BS"( K092142)

4. Device Description:

The Buttock Muscle Stimulator, model WL-2413E, is a two channel battery operated muscle stimulation system specifically designed to exercise the buttocks' muscle. The device comprises mainly the electronic stimulator module which generates the required stimulation signals.

The Buttock Muscle Stimulator, model WL-2413E, comprises a short with silicon pad electrodes which connect the signals from the stimulator to the skin. The electrodes are placed on the inner surface of the accessories. The product is supplied with a 510(K) cleared conductive gel, a user's manual, 3AAA batteries, 2 lead wires and a storage bag.

The required power of the device is derived from 3 batteries located in a compartment protected by a removable battery cover. The electrodes are in the inner surface of the shorts which is worn as shown on the picture of user manual. There is no current passed from side to side. The user cannot access the wiring or connectors within the shorts.

The Buttock Muscle Stimulator, model WL-2413E, is intended for use by healthy persons to apply transcutaneous electrical muscle stimulation(EMS) through skin contact electrode for the purpose of improvement of muscle tone of the buttocks muscles

5. Intended Use:

The Buttock Muscle Stimulator, model WL-2413E, is intended for use by healthy persons to apply transcutaneous electrical muscle stimulation(EMS) through skin contact electrode for the purpose of improvement of muscle tone of the buttocks muscles

6. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes IEC 60601-2-10, as well as IEC 60601-1, and IEC 60601-1-2 requirement.
In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

Discussion: The Compliance to applicable voluntary standards as above mentioned indicates that the new device in this submission used the same standards as that of predicate device in addition to the software validation standard. For our new device, the software validation was prepared according to FDA guidance, however the predicate device used IEC 60601-1-4 to prepare their software validation report. For this difference we believe that we used more adequate reference tool to prepare software validation report than the predicate device. Therefore; we consider that the compliance of standards included in our submission is adequate for the determination of substantial equivalence.

7. Comparison of Significant device features

| Comparison Features | Models to be Compared | |
|---|---|---|
| | SPORT-ELEC Body Control System | Buttock Muscle Stimulator |
| Model | "BS" | WL-2413E |
| 510(K) No. | K092142 | K123075 |
| Prescription or OTC | OTC | Same |
| Indication for use | intended for use by healthy persons to apply transcutaneous electrical muscle stimulation(EMS) through skin contact electrode for the purpose of improvement of muscle tone of the buttocks muscles | Same |
| FDA product code | NGX | Same |
| Electrode Used | Self Adhesive Electrode( 5 X 5 cm) | K082065, Silicon Pad Electrode ( 7.0 cm diameter) |
| Manufacturer | SPORT-ELECT | Well-Life |

## 8. Comparison of Unit Characteristics & Output Specification

| | | Predicate Device | New Device |
|---|---|---|---|
| Mode or Program Name | | BS | WL-2413E |
| Waveform (e.g., pulsed monophasic, biphasic) | | Biphasic | Biphasic |
| Shape (e.g., rectangular, spike, rectified sinusoidal) | | Rectangular | Rectangular |
| Maximum Output Voltage (volts)- (+/- 20 %) | | 31.2V @500Ω | 40.8V @500Ω |
| | | 66.0V @2kΩ | 70.0V @2kΩ |
| | | 66.0V @10kΩ | 106.0V @10kΩ |
| Maximum Output Current (mA)- (+/- 20 %) | | 62.4A @500Ω | 81.6mA @500Ω |
| | | 33.0A @2kΩ | 35.0mA @2kΩ |
| | | 6.6A @10kΩ | 10.6mA @10kΩ |
| Duration of primary phase (μsec) | | 200 Max | 300 Max |
| Pulse Duration (μsec) | | 540 Max. | 720 Max. |
| Frequency (Hz) [or Rate (pps)] | | 70 Max | 70 Max |
| For multiphasic waveforms only: | Symmetrical phases? | Yes | Yes |
| | Phase Duration (include units), (Stage range, if applicable), (both phases, if asymmetrical) | Not applicable | Not applicable |
| 510(K) Number | | K092142 | K123075 |
| Device Name and Model | | BS | WL-2413E |
| Manufacturer | | SPORT-ELECT | Well-Life |
| Power Source(s) | | 1.5Vx3 (AAA Size) | 1.5Vx3 (AAA Size) |
| - Method of Line current Isolation | | Type BF | Type BF |
| - Patient Leakage Current | | --- | --- |
| - Normal condition (μA) | | Under 0.1 | Under 0.1 |
| - single Fault condition (μA) | | Under 0.5 | Under 0.5 |
| Average DC current through electrodes when device is on but no pulses are being applied (μA) | | Not applicable | Not applicable |
| Number of Output Modes | | 4 | 4 |
| Number of Output Channels: | Synchronous or Alternating? | Synchronous | Synchronous |
| | Method of Channel Isolation | Output Coil | Output Coil |
| Regulated Current or Regulated Voltage? | | Voltage | Voltage |
| Software/Firmware/Microprocessor control? | | Yes | Yes |
| Automatic Overload Trip? | | No | No |
| Automatic No-Load Trip? | | Yes | Yes |
| Automatic Shut Off? | | Yes | Yes |
| User Override control? | | No | No |
| Indicator Display: | On/Off Status? | Yes | Yes |
| | Low Battery? | Yes | Yes |
| | Voltage/Current Level? | Yes | Yes |
| Timer Range (Minutes) | | 20-40 | 20-40 |
| Compliance with Voluntary Standards? | | IEC 60601-2-10 | IEC 60601-2-10 |
| Compliance with 21 CFR 898? | | Yes | Yes |
| Weight (g) including battery | | 171.6 | 80 |
| Dimensions (mm.) [W x H x D] | | 87×43×69 | 64×90×20 |
| Housing Materials and construction | | ABS | ABS |
| Pulse per burst | | Same for each program | Same for each program |
| Burst per second | | Same for each program | Same for each program |
| Bust duration | | Same for each program | Same for each program |
| Duty Cycle | | Same for each program | Same for each program |
| Method of achieving zero net charge for net charge/pulse | | Biphasic symmetric wave for each pulse | Biphasic symmetric wave for each pulse |

9. Significant output characteristics comparison table:

| Comparison feature | | Model | | Remarks |
|---|---|---|---|---|
| | | SPORT-ELECT BS | WL-2413E | |
| Net charge | | 0 | 0 | Note 1 |
| Max. phase charge | | 14 uc | 24 uc | |
| Max. current Density | | 0.0784 mA/cm$^2$ | 0.0997 mA/cm$^2$ | |
| Max. Average current (RMSA) | 500 Ω | 38.43mA | 38.644mA | |
| | 2K Ω | 14.892mA | 16.907 mA | |
| | 10 Ω | 4.996mA | 5.120 mA | |
| Max. Power Density | | 0.00274 Watts/ cm$^2$ | 0.00399 Watts/ cm$^2$ | |
| Burst Mode | | Yes | Yes | |

Note 1: Net Charge is Zero for the symmetrical stimulation biphasic wave

10. Summary for the technology comparison.

Basically the WL-2413E has the similar technological characteristics with the predicate device in the product design, material, energy source type, main program mode and the main output waveform...etc. There exist some difference in the detailed output parameters( mainly in the pulse duration and electrode sizes). Through the detailed calculation comparison of stimulation output energy for each operation mode(in particular the output current density and power density), we found the output level in each operation mode for our WL-2413E and predicate device are very close and within the acceptable range as specified in FDA guidance. So we believe the difference in detailed output parameters does not affect the determination of substantial equivalence.

11. Conclusions

The Buttock Muscle Stimulator, model: WL-2413E have the same intended use and the similar technological characteristics as the cleared device- SPORT-ELEC models Body Control System "BS"( K092142). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 11, 2013

Well-Life Healthcare Ltd
C/O Ms. Jenny Hsieh
1F, No. 16, Lane 454, Jungjeng Road
Yunghe City, Taipei County, Taiwan
R.O.C.

Re: K123075
Trade/Device Name: Well-Life Buttock Muscle Stimulator, model WL-2413E
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: June 2, 2013
Received: June 5, 2013

Dear Ms. Hsieh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K123075

Device Name: Well-Life Buttock Muscle Stimulator, model: WL 2413E

Indications For Use:

The Buttock Muscle Stimulator, model WL-2413E, is intended for use by healthy persons to apply transcutaneous electrical muscle stimulation(EMS) through skin contact electrode for the purpose of improvement of muscle tone of the buttocks muscles.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number _ K123075_____